13. (Once Amended) The portable ECG device of claim 11 wherein the information management system can broadcast ECG data to the health care facility as the patient is in transit.

REMARKS

In the Office Action mailed July 19, 2002, the Examiner rejected arguments traversing the claim election requirement imposed in the office action mailed June 4, 2000. As a result, the Examiner withdrew claims 16-35 from further consideration. The Examiner further rejected claims 1-15 under 35 U.S.C. §112, second paragraph, as being indefinite. Claims 1 and 2 were also rejected under 35 U.S.C. §102(b) as being anticipated by David et al. (USP 5,544,649). The Examiner rejected claims 1, 2, 4-6, 11-13 under 35 U.S.C. §102(b) as being anticipated by Bornn et al. (USP 5,564,429). Claims 3 and 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over David et al. Claims 7-9 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn et al. Claim 10 was rejected under 35 U.S.C. §103(a) as being unpatentable over David et al. Claim 10 was further rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn et al. Claims 14 and 15 were rejected under 35 U.S.C. §103(a) as being unpatentable over Bornn in view of Morgan et al. (USP 5,782,878).

The Examiner objected to the application for use of the term WebTV. Applicant has hereby amended the specification and the claims to replace WebTV appliance with "Internet appliance".

Claim Rejections – 35 U.S.C. §112

The Examiner rejected claims 1-15 under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter of the invention. The majority of the Examiner's rejections under § 112 rely on assertions that the claims are vague for citing a limitation which is "inferentially included and not positively recited in the claims." These rejections that rely on "inferentially claiming" are not sustainable and appear to stem from the Examiner's incorrect interpretation of the claims. However, Applicant will address each of the Examiner's assertions. As such, Applicant respectfully requests withdrawal of these rejections.

Initially, the Examiner stated that claim 1 contained a typographical error in that "cardiac condition of the patient" should read "of a cardiac condition of the patient." However, while the Examiner is correct that the ECG data produced by claim 1 can represent a single cardiac condition of the patient, it is also possible that the data will represent multiple cardiac conditions of the patient. It is intended that the condition could be singular or plural and therefore Applicant believes that the data can generally be representative "of cardiac condition of the patient."

Next, the Examiner rejected the claims under 35 U.S.C. §112 as being indefinite. The Examiner states that claim 1 is vague and indefinite for "inferentially" including "a plurality of lead wires" and "a healthcare provider." As one skilled in the art will readily recognize, "a healthcare provider" is not a required element of the claim. The claim merely states that a wireless communication interface is capable of transmitting the ECG data produced to a

healthcare provider. The important part of the claim limitation is the transmission of patient ECG data. Should Applicant delete "to a healthcare provider", the Examiner may then object to the claim for not stating where the transmission is destined. The claim also calls for an ECG monitor "connected to a plurality of lead wires." This is not inferentially claiming "a plurality of lead wires" — there is nothing to infer, as the ECG monitor is stated to be specifically connected to the plurality of lead wires. The Examiner appears to believe that every term used in the claims must be set forth as a separate paragraph. Such is not the case. Withdrawal of the rejections is requested, or in the alternative, Applicant requests citation to authority and support for the rejections.

The Examiner next states that claim 2 is vague and indefinite for citing the limitation "voice data". Again, claim 2 calls for "a wireless phone" that is capable of allowing voice data. Applicant believes that this claim as well satisfies §112 and is not incomplete as the Examiner states "for omitting an element to generate voice data." However, Applicant has amended claim 2 to clarify that the "wireless phone" is capable of allowing *audio* "and ECG data transmission concurrently."

Regarding the rejection to claim, Applicant has amended claim 3 to call for an Internet appliance as opposed to a WebTV appliance.

The Examiner next rejected claim 4 as "inferentially" including a data transmission link. Again, Applicant believes that this, and all other rejections that rely on "inferentially claiming" are not sustainable and Applicant respectfully requests withdrawal of these rejections. Claim 4 further defines how the processor may be programmed. As such, the Examiner's assertion that

"the claim is incomplete for omitting an element to "prompt the patient" (an indicator or the like) which would be the object of the processor's determination that assistance is required" is incorrect. The Examiner has mistakenly interpreted the claim. Claim 4 does not call for a method or apparatus to prompt the patient, rather it calls for a processor programmed to prompt the patient... One skilled in the art will readily understand the distinction.

The Examiner rejected claim 5 as being vague and indefinite for citing the limitation a desired transmission mode "since it is unclear whether the desired transmission mode is pre-determined or not." Applicant believes it is not important as to whether or not it is pre-determined, only that the portable ECG is programmed to allow selection of a desired transmission mode. The Examiner also rejected claim 5 as stating that the limitation "an audio communication data" is inferentially included and not positively recited in the claims. Applicant disagrees. The claim calls for a computer or a processor that is programmed to allow concurrent transmission of ECG data in addition to at least audio communication data. Applicant believes that this claim positively requires that the concurrent transmission of ECG data be in addition to audio communication data. Applicant believes that the Examiner is not interpreting the MPEP or the claims correctly and therefore believes that every claim rejected as "inferentially claiming" actually satisfies §112. The Examiner also states that the claim is "incomplete" for omitting an element to perform a desired transmission mode. Applicant believes that such is unnecessary. The claim is directed to an ECG device and specifies that the processor is programmed to allow certain acts. The claimed element is a processor programmed to perform certain acts irrespective

of any further hardware the Examiner believes might be necessary. Accordingly, Applicant believes that the claims are not incomplete.

Regarding claim 6, the Examiner rejected the claim stating that the limitation "video" is inferentially included and not positively recited. The claim is quite clear — claim 6 further defines claim 5 and requires that the processor be programmed to further include bi-directional video and audio transmissions with the transmission of ECG data. Regarding the inclusion of "video", the claim calls for the inclusion of the video and audio transmissions with the transmission of ECG data — this limitation is quite clear, and does not require any inferences, and therefore the Examiner's rejection is not sustainable. The Examiner also claims that this claim is incomplete. Again, the Examiner is not interpreting the claim correctly. The claim is calling for an ECG device wherein the processor is programmed to perform certain acts. Applicant believes that claim 6 also satisfies §112.

The Examiner next rejected claim 7 as vague and indefinite for citing the limitations "a video and audio monitor". Applicant believes that the Examiner is incorrect as the claim specifically calls for an interactive Internet appliance that is connectable to a video and audio monitor. Such is not inferentially claiming, but it is describing the interactive Internet appliance and its operating environment. Claim 7 does not require a video and audio monitor. Therefore, the claim does not inferentially include the video and audio monitor. The claim sets forth a portable ECG device that includes an interactive Internet appliance. A property of such an interactive Internet appliance is that it has the capability of connection to a video and audio monitor. The claim includes this capability. The Examiner also states that claim 7 is vague and

indefinite for claiming a limitation "a video camera and a microphone" and states that it is "unclear whether this is in addition to the video and audio monitor cited previously." However, Applicant believes that there is nothing unclear whatsoever. One skilled in the art can readily differentiate between "a video and audio monitor" and a "video camera and a microphone." Accordingly, Applicant believes that claim 7 is not vague or indefinite.

The Examiner next rejected claim 8 stating that "An inter-connected global computer system" was "inferentially included and not positively recited in the claims." Applicant disagrees. Applicant believes that the inter-connected global computer system is positively recited and claim 8 further specifies that the ECG data and the audio and video data are transmitted to the healthcare provider through an Internet global computer system. It is believed that claim 8 satisfies §112.

Claim 10 further specifies that the processor is further programmed to cause the infrared receiver to receive data instructions from the healthcare provider. This claim further defines how the processor is programmed. The claim calls for the infrared receiver to receive data instructions from the healthcare provider through the interactive Internet appliance. One skilled in the art will readily recognize that the claim is not vague or indefinite and therefore the claim satisfies §112.

The Examiner states that claim 12 is vague and indefinite as the Examiner is not "clear whether the data, the data storage element, the portable computer, or all three are 'downloadable at the healthcare facility'". Applicant does not believe the Examiner's interpretation of claim 12 is reasonable. Applicant believes that one skilled in the art will readily recognize that "data" is

downloadable. However, those skilled in the art will readily recognize that a data storage element or a portable computer would not be "downloadable."

The Examiner next states that claim 13 is vague and indefinite for citing the limitation "in transmit." Applicant has amended claim 13 to correct the typographical error.

Next, the Examiner rejected claim 15 as being vague and indefinite stating that "a signal" is inferentially included and not positively recited in the claims." However, again the Examiner incorrectly interprets the claim. Claim 15 calls for an ECG device wherein "the processor is programmed to receive a signal..." The claim calls for a limitation on how the processor is programmed. The claim further defines the processor programming to include the act of receiving a signal. Therefore, Applicant believes claim 15 clearly satisfies the requirements of §112.

Claim Rejections – 35 U.S.C. §102(b)

Substantively, the Examiner rejected claims 1 and 2 under 35 U.S.C. §102(b) "as being clearly anticipated by David et al. (USP 5,544,649)." The Examiner also rejected claims 1, 2, 4-6, and 11-13 under §102(b) "as being clearly anticipated by Bornn et al. (USP 5,564,429). However, the Examiner provided no basis or explanation of either of these §102(b) rejections. Applicant hereby respectfully requests reasoned statements by the Examiner demonstrating the Examiner's interpretation of the claims as to how the claims are "clearly anticipated" by the references cited. Since the Examiner failed to provide the required reasoning, Applicant requests any further action on this case be in non-final form.

To anticipate a claim, the reference must teach each and every element of the claim. See MPEP § 2131. Applicant believes one of ordinary skill in the art will readily acknowledge numerous distinctions between the current invention and the art cited by the Examiner. As stated, the Examiner did not provide any analysis or reasoning for the §102(b) rejections, and therefore, Applicant is not obligated to respond to unsubstantiated rejections. However, Applicant has chosen to highlight some of the clear distinctions in order to eliminate confusion.

Regardless of the suggested methods of communication between the devices in David, the reference does not teach the incorporation of each of the elements into a single unit, nor does the reference teach or refer to the transmission of data that has been processed. There is nothing in David to teach the incorporation of a wireless communication interface with an ECG (Electrocardiogram) monitor that has the ability to process the raw data received from the transducer included lead wires. Simply, David teaches that "the raw data is transmitted to the central station." Col. 7, lns. 45-46. and Col. 10, lns. 13-19. David teaches that only the central station "includes all of the needed sophistication to allow for the storage, transformation, display and interpretation of the data." Col. 7, lns. 46-48. As such, it is clear that unlike the current invention, David teaches no data processing prior to transmission.

Nevertheless, Applicant has amended claim 1 clarify the invention. As such, claim 1 has been amended to clarify that the ECG monitor is a "portable, on-demand" monitor. Furthermore, Applicant has amended the claim to clarify that the ECG signals received from the patient are "*in a standard 12-lead configuration*" and the plurality of leads produces "*standard 12-lead* ECG data representative of cardiac condition of the patient."

Regarding the Examiner's rejection of claim 1 as unpatentable over David, Applicant believes the current invention to be distinguishable on additional basis. The configuration disclosed in David is incapable of portability. The cumbersome equipment required for television broadcast in conjunction the ECG equipment attached to a chair make extensive patient movement impractical. Not only did claim 1 call for a "portable ECG device" in the preamble, it now also calls for "a portable, on-demand ECG monitor " in the body of the claim. Accordingly, Applicant believes claim 1 to be readily distinguishable from David.

Furthermore, regarding the rejection of claim 1 as unpatentable over Bornn, Applicant believes the current invention to be distinguishable. Claim 1, in part, calls for "a portable, on-demand ECG monitor." Bornn clearly teaches away from the ECG monitor being "on-demand." Bornn teaches that the patient must wear "a torso band and an optional shoulder band." Col. 4, lns. 5-6. Should the patient move beyond communications range or remove the torso band the monitor will enter an alert condition. Col. 3, lns. 15-52 and Col. 4, lns. 3-25. A patient must reenter the communications range and/or replace the torso band within a permissible time interval in order to avoid conveying a false positive indication to the central station. Col. 3, lns 15-25. Simply, the ECG monitor taught in Bornn is not on-demand because a patient does not have the option to use the ECG monitor at his or her discretion. The patient must continuously wear the torso band and stay within the bounds of operating conditions in order to avoid false positives. On the other hand, the current invention calls for an on-demand ECG monitor, thus allowing the patient to choose when or when not to use the ECG monitor. This on-demand nature of the

current invention effectivcly renders any grace period to allow a patient to reenter the communication range unnccessary.

Furthermore, the current invention calls the reception of ECG signals from the patient "in a standard 12-lcad configuration" and for the production of "standard 12-lcad ECG data reprcsentative of cardiac condition of the patient." Bornn teaches directly away from the reception of data from the patient in standard 12-lcad configuration and thc production of standard 12-lead ECG data. Bornn discloses the usc of "pairs of electrodcs" in various configurations. Col. 9, lns. 10-30 and Col. 10, lns. 1-6. One skilled in the art will immediately recognize that use of "pairs of clectrodes" is indicativc of bi-polar electrodcs. Standard 12-lead ECG data is acquircd from uni-polar electrodes. Thus, Bornn is not capable of a standard 12-lead ECG data output.

Also, Bornn tcaches the usc of "a torso band and an optional shoulder band." Col. 4, lns. 5-6. The bands are clearly shown in Figures 1A and 2A of Bornn. Onc skilled in the art will recognize that the electrodc placement consistent with the bands disclosed in Bornn is incapable of producing standard 12-lcad ECG data as called for in claim 1. As such, Applicant believes claim 1 to be readily distinguishable from Bornn and defines ovcr the art of record.

For all of thc above rcasons, Applicant believcs claim 1 to be in condition for allowance. Accordingly, Applicant believcs the Examiner's §102(b) rejection of claims 2, 4-6, and 11-13 are not sustainable. Therefore, Applicant request Notice of Allowancc for claims 2, 4-6, and 11-13 pursuant to the chain of dependency.

Claim Rejections – 35 U.S.C. 103(a)

Regarding the Examiner's rejection of claims 3, 7-9, and 10 under 35 U.S.C. §103(a), Applicant respectfully disagrees with the Examiner with respect to the art. In light of each of the aforementioned claims depending from what is believed an otherwise allowable claim, Applicant does not believe additional remarks are necessary and therefore requests a Notice of Allowance for claims 3, 7-9, and 10 pursuant to the chain of dependency.

Therefore, in light of the foregoing, Applicant respectfully believes that the present application is in condition for allowance. As a result, Applicant respectfully requests timely issuance of a Notice of Allowance for claims 1-15.

Marked-up versions of the amendments made above may be found on pages 17-20.

Applicant appreciates the Examiner's consideration of these Amendments and Remarks and cordially invites the Examiner to call the undersigned, should the Examiner consider any matters unresolved.

Respectfully submitted,

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Date: November 19, 2002
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REVISIONS

IN THE SPECIFICATION:

Referring to Fig. 4, a second embodiment of the present invention is disclosed. Again, patient 180 is connected to the ECG device 184, of the present invention, which preferably includes a 12-channel ECG device, such as the aforementioned GE Marquette MacVu or Seer-MC equipped with 12SL™. However, in this embodiment, the wireless communication device is an interactive Internet appliance such as an interactive ~~Web~~Internet TV appliance 210, capable of allowing voice, video and ECG data transmission through an interconnected global computer system, such as the Internet 212. The ECG device 184 and the ~~Web~~Internet TV appliance 210 transmits data therebetween through an infrared transmission 214. Accordingly, the ECG device 184 is equipped with an infrared transmitter and the ~~Web~~Internet TV appliance is equipped with an infrared receiver, as described with reference to Fig. 1. The ~~Web~~Internet TV appliance 210 can also receive data instructions from the centralized facility or health care provider 190 through the ~~Web~~Internet TV appliance 210. The ~~Web~~Internet TV appliance 210 is connected to a television 216 to display visual signals 218 and audio signals 220 to patient 180.

Preferably, the ~~Web~~Internet TV appliance 210 is equipped with a video camera 222 and a microphone 224 to receive and transmit audio and video signals from patient 180 to the centralized facility 190. In this manner, the processor in the ECG device 184 is programmed to allow concurrent transmission of ECG data, voice data, and video data, wherein the video and audio transmissions may be bi-directional. That is, since the voice, video, and ECG signals are

communicated in real time, or near real time, from the remote location 182 to the centralized facility 190, which may be a hospital, the centralized facility 190 is thereby equipped with a ~~Web~~Internet computer 226 that is, in turn, connected to a television 228, also equipped with a microphone 230 and a video camera 232 to transmit images and audio from a doctor or clinician 240. Similar to the embodiment of Fig. 3, the doctor or clinician at the centralized facility 190, Fig. 4, can listen to and talk to the patient 180 remotely while observing the patient's ECG waveforms. Also similar to the embodiment of Fig. 3, the ECG/display 206 receives data from the local communication interface 226. If the data has already been processed, it can go directly to the printer 208, or if the ECG of the centralized facility is processing the data, the signals go through the ECG 206, then to the printer 208. The patient's file is then updated 204.

Referring to Fig. 5, a detailed flow chart of the software programmed into the portable ECG device is shown. Once the ECG is initiated 250, the program checks to see if the patient requests assistance with using the ECG device 252. If so 254, the auto-dial feature of the mobile phone is initiated or the ~~Web~~Internet TV interface is prompted 256, at which time communication is permitted between the health care provider, or centralized facility, and the patient 258. Once the assistance is complete 260, or the patient did not require assistance 252, 262, the ECG signals are acquired 264, processed 266, and prepared for transmission at 268. The desired mode of transmission is then selected at 270 to allow concurrent transmission of ECG data and at least voice communication.

If the ~~Web~~Internet TV mode is selected 270, 272, the ECG transmits the data to the ~~Web~~Internet TV device 274 and allows audiovisual communication 276. Conversely, if the

wireless phone transmission mode is selected 270, 278, the auto-dial feature is enabled, if not already connected 280, and the ECG transmits the data at 282, thereby allowing bi-directional voice communication 284. At this point, regardless of whether the wireless phone transmission mode is selected 278 or the ~~Web~~Internet TV mode is selected 272, the ECG device is enabled to receive instructions 286 from the centralized facility. If the ECG is instructed to acquire more data 288, 290 the process is repeated. If not 288, 292, the ECG subroutine is complete 294.

With the use of an ~~Web~~Internet TV appliance, the centralized facility can be relatively assured that the patient is located at the patient's house during use. However, the same cannot be said for the wireless phone transmission mode. In this instance, the method can include confirming a location of the patient before dispatching emergency personnel. This can be done through telephone communication, but if the patient should experience a heart attack and become unconscious, an alternative method must be provided. In this instance, the confirmation step includes receiving a GPS guidance signal from the ECG device indicative of the location of the patient. Accordingly, the ECG device optionally includes a GPS guidance system. The guidance system is initialized by the centralized facility which sends the GPS initialization signal to the ECG device, and once received, the ECG device transmits a GPS guidance signal from the ECG device to a global satellite system, which in turn, transmits a location of the patient to the centralized facility.

IN THE CLAIMS:

1. (Once Amended) A portable ECG device comprising:

an portable, on-demand ECG monitor connected to a plurality of lead wires, each lead wire having a transducer capable of receiving an ECG signal from a patient in a standard 12-lead configuration, the ECG monitor having a processor to process the ECG signals from the plurality of lead wires and produce standard 12-lead ECG data representative of cardiac condition of the patient;

a wireless communication interface coupled to receive patient ECG data from the ECG monitor and to transmit patient ECG data to a health care provider.

2. (Once Amended) The portable ECG device of claim 1 wherein the wireless communication interface is a wireless phone capable of allowing ~~voice~~ audio and ECG data transmission concurrently.

3. (Once Amended) The portable ECG device of claim 1 wherein the wireless communication interface is an interactive ~~Web~~Internet TV appliance capable of allowing voice, video and ECG data transmission concurrently.

13. (Once Amended) The portable ECG device of claim 11 wherein the information management system can broadcast ECG data to the health care facility as the patient is in ~~transmit~~transit.